

Rx ONLY.

Caution: Federal Law (USA) restricts this device to sale by or on the order of a physician

WARNING

Contents supplied STERILE using a EO sterilization process. Do not use if sterile barrier is damaged.

Use the catheter prior to the "Use By" date specified on the package.

For single use only. Do not reuse, reprocess or resterilize. Reuse, reprocessing or resterilization may compromise the structural integrity of the device and/or lead to device failure which, in turn, may result in patient injury, illness or death. Reuse, reprocessing or reserialization may also create a risk of contamination of the device and/or cause patient infection or cross-infection, including, but not limited to, the transmission of infectious disease(s) from one patient to another. Contamination of the device may lead to injury, illness or death of the patient

DEVICE DESCRIPTION

The Peripheral Scoring Balloon Dilatation Catheter features a non-compliant balloon with 3 scoring elements mounted longitudinally on its outer surface. When the Peripheral Scoring Balloon Dilatation Catheter is inflated, the scoring elements score intima tissue to achieve the purpose of treatment. It is designed to improve the lumen diameter of obstructive lesions in peripheral vessels.

The Peripheral Scoring Balloon Dilatation Catheter is an over the wire (OTW), high performance, double-lumen catheter. 3 scoring elements between the two marker bands are evenly circle mounted on the surface of the balloon. The catheter has two independent lumens, one lumen is used for filling the balloon, and the other lumen is used for guide wire insertion. There are two radiopaque marker bands in the balloon for positioning, which indicates the expanded part of the balloon and helps in the placement of the balloon.

The diameter and length of the balloon and the diameter of the compatible guide wire are printed on the seat.

The sterile barrier system of the product contains a protective hoop to hold the catheter.

SIZE

NO.	Model Number	Balloon Nominal Diameter (mm)	Balloon Nominal Length (mm)	Catheter length (cm)	Balloon Nominal Pressure (atm)	Rated Burst Pressure (atm)
1	DKL14-2520B	2.5	20	90	10	14
2	DKL14-2540B	2.5	40	90	10	14
3	DKL14-2560B	2.5	60	90	10	14
4	DKL14-2580B	2.5	80	90	10	14
5	DKL14-25100B	2.5	100	90	10	14
6	DKL14-25120B	2.5	120	90	10	14
7	DKL14-25150B	2.5	150	90	10	14
8	DKL14-2520C	2.5	20	135	10	14
9	DKL14-2540C	2.5	40	135	10	14
10	DKL14-2560C	2.5	60	135	10	14

NO.	Model Number	Balloon Nominal Diameter (mm)	Balloon Nominal Length (mm)	Catheter length (cm)	Balloon Nominal Pressure (atm)	Rated Burst Pressure (atm)
11	DKL14-2580C	2.5	80	135	10	14
12	DKL14-25100C	2.5	100	135	10	14
13	DKL14-25120C	2.5	120	135	10	14
14	DKL14-25150C	2.5	150	135	10	14
15	DKL14-2520D	2.5	20	150	10	14
16	DKL14-2540D	2.5	40	150	10	14
17	DKL14-2560D	2.5	60	150	10	14
18	DKL14-2580D	2.5	80	150	10	14
19	DKL14-25100D	2.5	100	150	10	14
20	DKL14-25120D	2.5	120	150	10	14
21	DKL14-25150D	2.5	150	150	10	14
22	DKL14-3020B	3.0	20	90	10	14
23	DKL14-3040B	3.0	40	90	10	14
24	DKL14-3060B	3.0	60	90	10	14
25	DKL14-3080B	3.0	80	90	10	14
26	DKL14-30100B	3.0	100	90	10	14
27	DKL14-30120B	3.0	120	90	10	14
28	DKL14-30150B	3.0	150	90	10	14
29	DKL14-3020C	3.0	20	135	10	14
30	DKL14-3040C	3.0	40	135	10	14
31	DKL14-3060C	3.0	60	135	10	14
32	DKL14-3080C	3.0	80	135	10	14
33	DKL14-30100C	3.0	100	135	10	14
34	DKL14-30120C	3.0	120	135	10	14
35	DKL14-30150C	3.0	150	135	10	14
36	DKL14-3020D	3.0	20	150	10	14
37	DKL14-3040D	3.0	40	150	10	14
38	DKL14-3060D	3.0	60	150	10	14
39	DKL14-3080D	3.0	80	150	10	14
40	DKL14-30100D	3.0	100	150	10	14
41	DKL14-30120D	3.0	120	150	10	14
42	DKL14-30150D	3.0	150	150	10	14
43	DKL14-3520B	3.5	20	90	10	14

NO.	Model Number	Balloon Nominal Diameter (mm)	Balloon Nominal Length (mm)	Catheter length (cm)	Balloon Nominal Pressure (atm)	Rated Burst Pressure (atm)
44	DKL14-3540B	3.5	40	90	10	14
45	DKL14-3560B	3.5	60	90	10	14
46	DKL14-3580B	3.5	80	90	10	14
47	DKL14-35100B	3.5	100	90	10	14
48	DKL14-35120B	3.5	120	90	10	14
49	DKL14-35150B	3.5	150	90	10	14
50	DKL14-3520C	3.5	20	135	10	14
51	DKL14-3540C	3.5	40	135	10	14
52	DKL14-3560C	3.5	60	135	10	14
53	DKL14-3580C	3.5	80	135	10	14
54	DKL14-35100C	3.5	100	135	10	14
55	DKL14-35120C	3.5	120	135	10	14
56	DKL14-35150C	3.5	150	135	10	14
57	DKL14-3520D	3.5	20	150	10	14
58	DKL14-3540D	3.5	40	150	10	14
59	DKL14-3560D	3.5	60	150	10	14
60	DKL14-3580D	3.5	80	150	10	14
61	DKL14-35100D	3.5	100	150	10	14
62	DKL14-35120D	3.5	120	150	10	14
63	DKL14-35150D	3.5	150	150	10	14
64	DKL18-4020B	4.0	20	90	10	14
65	DKL18-4040B	4.0	40	90	10	14
66	DKL18-4060B	4.0	60	90	10	14
67	DKL18-4080B	4.0	80	90	10	14
68	DKL18-40100B	4.0	100	90	10	14
69	DKL18-40120B	4.0	120	90	10	14
70	DKL18-40150B	4.0	150	90	10	14
71	DKL18-4020C	4.0	20	135	10	14
72	DKL18-4040C	4.0	40	135	10	14
73	DKL18-4060C	4.0	60	135	10	14
74	DKL18-4080C	4.0	80	135	10	14
75	DKL18-40100C	4.0	100	135	10	14
76	DKL18-40120C	4.0	120	135	10	14

NO.	Model Number	Balloon Nominal Diameter (mm)	Balloon Nominal Length (mm)	Catheter length (cm)	Balloon Nominal Pressure (atm)	Rated Burst Pressure (atm)
77	DKL18-40150C	4.0	150	135	10	14
78	DKL18-4020D	4.0	20	150	10	14
79	DKL18-4040D	4.0	40	150	10	14
80	DKL18-4060D	4.0	60	150	10	14
81	DKL18-4080D	4.0	80	150	10	14
82	DKL18-40100D	4.0	100	150	10	14
83	DKL18-40120D	4.0	120	150	10	14
84	DKL18-40150D	4.0	150	150	10	14
85	DKL18-4520B	4.5	20	90	10	14
86	DKL18-4540B	4.5	40	90	10	14
87	DKL18-4560B	4.5	60	90	10	14
88	DKL18-4580B	4.5	80	90	10	14
89	DKL18-45100B	4.5	100	90	10	14
90	DKL18-45120B	4.5	120	90	10	14
91	DKL18-45150B	4.5	150	90	10	14
92	DKL18-4520C	4.5	20	135	10	14
93	DKL18-4540C	4.5	40	135	10	14
94	DKL18-4560C	4.5	60	135	10	14
95	DKL18-4580C	4.5	80	135	10	14
96	DKL18-45100C	4.5	100	135	10	14
97	DKL18-45120C	4.5	120	135	10	14
98	DKL18-45150C	4.5	150	135	10	14
99	DKL18-4520D	4.5	20	150	10	14
100	DKL18-4540D	4.5	40	150	10	14
101	DKL18-4560D	4.5	60	150	10	14
102	DKL18-4580D	4.5	80	150	10	14
103	DKL18-45100D	4.5	100	150	10	14
104	DKL18-45120D	4.5	120	150	10	14
105	DKL18-45150D	4.5	150	150	10	14
106	DKL18-5020B	5.0	20	90	10	14
107	DKL18-5040B	5.0	40	90	10	14
108	DKL18-5060B	5.0	60	90	10	14
109	DKL18-5080B	5.0	80	90	10	14

NO.	Model Number	Balloon Nominal Diameter (mm)	Balloon Nominal Length (mm)	Catheter length (cm)	Balloon Nominal Pressure (atm)	Rated Burst Pressure (atm)
110	DKL18-50100B	5.0	100	90	10	14
111	DKL18-50120B	5.0	120	90	10	14
112	DKL18-50150B	5.0	150	90	10	14
113	DKL18-5020C	5.0	20	135	10	14
114	DKL18-5040C	5.0	40	135	10	14
115	DKL18-5060C	5.0	60	135	10	14
116	DKL18-5080C	5.0	80	135	10	14
117	DKL18-50100C	5.0	100	135	10	14
118	DKL18-50120C	5.0	120	135	10	14
119	DKL18-50150C	5.0	150	135	10	14
120	DKL18-5020D	5.0	20	150	10	14
121	DKL18-5040D	5.0	40	150	10	14
122	DKL18-5060D	5.0	60	150	10	14
123	DKL18-5080D	5.0	80	150	10	14
124	DKL18-50100D	5.0	100	150	10	14
125	DKL18-50120D	5.0	120	150	10	14
126	DKL18-50150D	5.0	150	150	10	14
127	DKL18-5520B	5.5	20	90	10	14
128	DKL18-5540B	5.5	40	90	10	14
129	DKL18-5560B	5.5	60	90	10	14
130	DKL18-5580B	5.5	80	90	10	14
131	DKL18-55100B	5.5	100	90	10	14
132	DKL18-55120B	5.5	120	90	10	14
133	DKL18-55150B	5.5	150	90	10	14
134	DKL18-5520C	5.5	20	135	10	14
135	DKL18-5540C	5.5	40	135	10	14
136	DKL18-5560C	5.5	60	135	10	14
137	DKL18-5580C	5.5	80	135	10	14
138	DKL18-55100C	5.5	100	135	10	14
139	DKL18-55120C	5.5	120	135	10	14
140	DKL18-55150C	5.5	150	135	10	14
141	DKL18-5520D	5.5	20	150	10	14
142	DKL18-5540D	5.5	40	150	10	14

NO.	Model Number	Balloon Nominal Diameter (mm)	Balloon Nominal Length (mm)	Catheter length (cm)	Balloon Nominal Pressure (atm)	Rated Burst Pressure (atm)
143	DKL18-5560D	5.5	60	150	10	14
144	DKL18-5580D	5.5	80	150	10	14
145	DKL18-55100D	5.5	100	150	10	14
146	DKL18-55120D	5.5	120	150	10	14
147	DKL18-55150D	5.5	150	150	10	14
148	DKL18-6020B	6.0	20	90	10	14
149	DKL18-6040B	6.0	40	90	10	14
150	DKL18-6060B	6.0	60	90	10	14
151	DKL18-6080B	6.0	80	90	10	14
152	DKL18-60100B	6.0	100	90	10	14
153	DKL18-60120B	6.0	120	90	10	14
154	DKL18-60150B	6.0	150	90	10	14
155	DKL18-6020C	6.0	20	135	10	14
156	DKL18-6040C	6.0	40	135	10	14
157	DKL18-6060C	6.0	60	135	10	14
158	DKL18-6080C	6.0	80	135	10	14
159	DKL18-60100C	6.0	100	135	10	14
160	DKL18-60120C	6.0	120	135	10	14
161	DKL18-60150C	6.0	150	135	10	14
162	DKL18-6020D	6.0	20	150	10	14
163	DKL18-6040D	6.0	40	150	10	14
164	DKL18-6060D	6.0	60	150	10	14
165	DKL18-6080D	6.0	80	150	10	14
166	DKL18-60100D	6.0	100	150	10	14
167	DKL18-60120D	6.0	120	150	10	14
168	DKL18-60150D	6.0	150	150	10	14
169	DKL18-6520B	6.5	20	90	10	14
170	DKL18-6540B	6.5	40	90	10	14
171	DKL18-6560B	6.5	60	90	10	14
172	DKL18-6580B	6.5	80	90	10	14
173	DKL18-65100B	6.5	100	90	10	14
174	DKL18-65120B	6.5	120	90	10	14
175	DKL18-65150B	6.5	150	90	10	14

NO.	Model Number	Balloon Nominal Diameter (mm)	Balloon Nominal Length (mm)	Catheter length (cm)	Balloon Nominal Pressure (atm)	Rated Burst Pressure (atm)
176	DKL18-6520C	6.5	20	135	10	14
177	DKL18-6540C	6.5	40	135	10	14
178	DKL18-6560C	6.5	60	135	10	14
179	DKL18-6580C	6.5	80	135	10	14
180	DKL18-65100C	6.5	100	135	10	14
181	DKL18-65120C	6.5	120	135	10	14
182	DKL18-65150C	6.5	150	135	10	14
183	DKL18-6520D	6.5	20	150	10	14
184	DKL18-6540D	6.5	40	150	10	14
185	DKL18-6560D	6.5	60	150	10	14
186	DKL18-6580D	6.5	80	150	10	14
187	DKL18-65100D	6.5	100	150	10	14
188	DKL18-65120D	6.5	120	150	10	14
189	DKL18-65150D	6.5	150	150	10	14
190	DKL18-7020B	7.0	20	90	10	14
191	DKL18-7040B	7.0	40	90	10	14
192	DKL18-7060B	7.0	60	90	10	14
193	DKL18-7080B	7.0	80	90	10	14
194	DKL18-70100B	7.0	100	90	10	14
195	DKL18-70120B	7.0	120	90	10	14
196	DKL18-70150B	7.0	150	90	10	14
197	DKL18-7020C	7.0	20	135	10	14
198	DKL18-7040C	7.0	40	135	10	14
199	DKL18-7060C	7.0	60	135	10	14
200	DKL18-7080C	7.0	80	135	10	14
201	DKL18-70100C	7.0	100	135	10	14
202	DKL18-70120C	7.0	120	135	10	14
203	DKL18-70150C	7.0	150	135	10	14
204	DKL18-7020D	7.0	20	150	10	14
205	DKL18-7040D	7.0	40	150	10	14
206	DKL18-7060D	7.0	60	150	10	14
207	DKL18-7080D	7.0	80	150	10	14
208	DKL18-70100D	7.0	100	150	10	14

NO.	Model Number	Balloon Nominal Diameter (mm)	Balloon Nominal Length (mm)	Catheter length (cm)	Balloon Nominal Pressure (atm)	Rated Burst Pressure (atm)
209	DKL18-70120D	7.0	120	150	10	14
210	DKL18-70150D	7.0	150	150	10	14

The size of product is consisted with the serial, diameter of guidewire, nominal diameter of balloon, nominal length of balloon and length of catheter.

For example:

Model Number	DKL	18	-	70	20	D
Explanation	series code	DOW	-	DOB	LOB	LOC

Where

- DKL: Represents the series code
- DOW: Represents the diameter of guidewire, there is a total 2 options which is 18 and 14 and it represents the diameter of guidewire is 0.018inch and 0.014inch respectively.
- DOB: Represents the nominal diameter of balloon, there is a total 10 options which is 25, 30, 35, 40, 45, 50, 55, 60, 65, 70 and it represents the nominal diameter of balloon is 2.5mm, 3.0mm, 3.5mm, 4.0mm, 4.5mm, 5.0mm, 5.5mm, 6.0mm, 6.5mm, 7.0mm respectively.
- LOB: Represents the nominal length of balloon, there is a total 7 options which is 20, 40, 60, 80, 100, 120, 150 and it represents the nominal length of balloon is 20mm, 40mm, 60mm, 80mm, 100mm, 120mm, 150mm respectively.
- LOC: Represents the length of catheter, there is a total 3 options which is B, C and D and it represents the length of catheter is 90cm, 135cm and 150cm respectively.

INTENDED PURPOSE

To perform Percutaneous Transluminal Angioplasty (PTA) in the peripheral vasculature, using three scoring elements along the balloon length.

INDICATIONS FOR USE

The Peripheral Scoring Balloon Dilatation Catheter is indicated for the treatment of obstructive lesions of the peripheral vasculature, including complex lesion morphologies.

INTENDED USER

Physicians with adequate training in performance of percutaneous transluminal angioplasty.

INTENDED PATIENT POPULATION

The intended population is adult patients who are eligible for Percutaneous Transluminal Angioplasty (PTA) procedure.

CLINICAL BENEFIT

The use of the Peripheral Scoring Balloon Dilatation Catheter is to dilate stenotic lesions in the peripheral vasculature and improves blood perfusion.

CONTRAINDICATIONS

- Use of the Peripheral Scoring Balloon Dilatation Catheter is contraindicated in situations where the Peripheral Scoring Balloon Dilatation Catheter would be passed through the struts of a previously placed stent as the deflated Peripheral Scoring Balloon Dilatation Catheter could become entangled in the stent.
 - The Peripheral Scoring Balloon Dilatation Catheter is not for use in the coronary arteries and carotid arteries.
 - The Peripheral Scoring Balloon Dilatation Catheter is not intended for the expansion or delivery of stents.
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WARNINGS

- Angioplasty with the Peripheral Scoring Balloon Dilatation Catheter, because of its mechanism of action, may pose a greater risk of perforation than that observed with conventional PTA. Oversizing increases the risk of perforation. To reduce the potential for vessel damage the inflated diameter of the Peripheral Scoring Balloon Dilatation Catheter should not exceed a 1.1:1 ratio of the diameter of the vessel just proximal and distal to the stenosis.
 - Balloon pressure should not exceed the rated burst pressure. The rated burst pressure is based on the results of *in vitro* testing. At least 99.9% of the balloons (with a 95% confidence) will not burst at or below their rated burst pressure. Use of a pressure monitoring device is recommended to prevent over pressurization.
 - Use only the recommended balloon inflation medium (e.g. - contrast medium). Never use air or any gaseous medium to inflate the balloon.
 - Do not use in a kinked or buckled introducer sheath or if resistance is encountered. Resistance, kinking, or buckling in the introducer sheath may damage the scoring elements or balloon. If any of these occur, immediately withdraw both devices.
 - When the catheter is exposed to the vascular system, it should be manipulated while under high-quality fluoroscopic observation. Do not advance or retract the catheter unless the balloon is fully deflated under vacuum. If resistance is met during manipulation, determine the cause of the resistance before proceeding.
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PRECAUTIONS

- Prior to angioplasty, the catheter should be examined to verify functionality and ensure that its size and shape are suitable for the specific procedure for which it is to be used.
 - Only physicians who have received the appropriate training should use the Peripheral Scoring Balloon Dilatation Catheter.
 - During the Peripheral Scoring Balloon Dilatation Catheter procedure, appropriate anticoagulant therapy should be provided to the patient. Anticoagulant therapy should be continued for a period of time after the procedure to be determined by the physician.
 - The Peripheral Scoring Balloon Dilatation Catheter is not designed for, and therefore, cannot be used to monitor *in vivo* arterial pressures.
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POTENTIAL ADVERSE EVENTS

Risks associated with interventional treatment of stenosis with the Peripheral Scoring Balloon Dilatation Catheter are similar to those of conventional PTA. Potential risks include, but are not limited to:

- Allergic or drug reaction (device material, contrast medium and medications)

- Amputation
 - Arteriovenous fistula
 - Death
 - Embolism
 - Hematoma
 - Hemorrhage
 - Hypotension/hypertension
 - Infection/Sepsis
 - Ischemia/infarction of tissue/organ
 - Pain
 - Pseudoaneurysm
 - Restenosis
 - Surgical intervention
 - Swelling
 - Thrombosis
 - Vascular occlusion
 - Vessel injury (dissection, perforation, or rupture)
 - Vessel spasm
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OPERATIONAL INSTRUCTIONS

Preparation Technique

Prior to use, carefully examine the unit to verify that the catheter and sterile package have not been damaged in shipment.

Using sterile technique, remove the Peripheral Scoring Balloon Dilatation Catheter from its package and place onto the sterile field. Do not remove the catheter from its protective hoop at this time.

As supplied, the balloon lumen of the device contains air. This air must be displaced to make certain that only liquid fills the balloon while the catheter is in the bloodstream.

To displace air

1. Connect a three-way stopcock to the balloon lumen. Turn the stopcock lever off to the balloon;
2. Fill a 20 ml (20 cc) syringe with approximately 4 ml (4 cc) of a mixture of contrast medium and normal saline;
3. Attach syringe to the three-way stopcock on the balloon lumen. Purge the stopcock by flushing the mixture of contrast medium and saline through the middle port;
4. Open the stopcock to the balloon. Draw back on the syringe to its full volume deflating the balloon and drawing air bubbles into the syringe barrel;
5. To make certain that all air is removed from the balloon, repeat step 4;
6. Close the stopcock to the balloon;
7. Remove the Peripheral Scoring Balloon Dilatation Catheter from its protective ring. Discard the protective hoop. Using straight force (not a twisting motion), pull the protective sheath off the balloon;
8. Flush the guidewire lumen of the Peripheral Scoring Balloon Dilatation Catheter with heparinized saline.

Catheter Insertion

Introduce the Peripheral Scoring Balloon Dilatation Catheter percutaneously by Seldinger technique, using the 7Fr introducer sheath.

1. Insert a suitable guidewire through the Peripheral Scoring Balloon Dilatation Catheter guidewire lumen.
2. Gently grasp the proximal portion of the balloon at the shaft. Advance the Peripheral Scoring Balloon Dilatation Catheter through the introducer sheath, avoiding excessive pressure on the balloon as you advance it through the hemostasis valve to avoid unwanted contact with the scoring elements.
3. Under fluoroscopy, position the balloon so that the lesion is centered between the radiopaque markers on the balloon.

Caution: Do not advance the guidewire or the Peripheral Scoring Balloon Dilatation Catheter if the sheath is kinked, buckled or offers resistance.

Balloon Inflation

Use an inflation device with a pressure gauge to monitor pressure within the balloon to determine that adequate dilatation force is applied while not exceeding the maximum limits of the product.

1. Under fluoroscopy, slowly inflate the Peripheral Scoring Balloon Dilatation Catheter 1 atm (101 kPa) every 5 seconds until balloon indentation is no longer visible. Do not inflate the Peripheral Scoring Balloon Dilatation Catheter above 14 atm (1418 kPa). Hold inflation for 60 to 90 seconds. After dilating the lesion, slowly deflate the Peripheral Scoring Balloon Dilatation Catheter 1 atm (101 kPa) every 5 seconds.

Caution: Rapid deflation may compromise refold.

2. When using the on long lesion segments the distal portion(s) of the target lesion should be treated first. Then, overlapping dilation of the proximal lesion segment may be performed.

Caution: Optimal balloon refold depends upon many factors, including handling, vessel anatomy, lesion composition, inflation pressure, and number of inflations.

3. The standard inflation medium is a 1 :1 mixture of contrast medium and normal saline. Do not use air or any gaseous substances as a balloon inflation medium.
4. Do not exceed rated burst pressure of 14 atm (1418 kPa) during this process. Inflation in excess of rated burst pressure may cause the balloon to rupture. If loss of pressure within the balloon occurs during inflation or if balloon ruptures during dilation, immediately discontinue the procedure and deflate the balloon. Do not re-inflate; remove carefully.

Caution: The minimal dilating force required to dilate should be applied, minimizing risks of balloon over-inflation or rupture.

Caution: Appropriate sizing of the Peripheral Scoring Balloon Dilatation Catheter is extremely important. Do not exceed a balloon to vessel ratio of 1.1:1.

Balloon Diameter to Inflation Pressures (Balloon Compliance)

Balloon Nominal Diameter (mm)	/	Pressure (atm)		
		(NP) 10	12	(RBP) 14
2.5	Balloon Diameter At Each Pressure	2.50	2.54	2.57
3.0		3.00	3.04	3.08
3.5		3.50	3.55	3.60
4.0		4.00	4.11	4.17

Balloon Nominal Diameter (mm)	/ (mm)	Pressure (atm)		
		(NP) 10	12	(RBP) 14
4.5	(mm)	4.50	4.62	4.69
5.0		5.00	5.18	5.26
5.5		5.50	5.79	5.91
6.0		6.00	6.19	6.27
6.5		6.50	6.75	6.85
7.0		7.00	7.21	7.29

NP: Nominal Pressure

RBP: Rated Burst Pressure

Catheter Withdrawal

Deflate the Peripheral Scoring Balloon Dilatation Catheter by applying vacuum with the inflation/deflation device.

Maintain vacuum on the Peripheral Scoring Balloon Dilatation Catheter and verify deflation with fluoroscopy. Withdraw the Peripheral Scoring Balloon Dilatation Catheter from the lesion.

Repeat angiography to confirm successful result.

Withdraw the Peripheral Scoring Balloon Dilatation Catheter from the introducer sheath.

Caution: After removal from the introducer sheath, do not re-insert the Peripheral Scoring Balloon Dilatation Catheter.

Caution: If resistance is encountered when removing the catheter through an introducer sheath or a guidewire through the catheter, stop and remove them as a complete unit to prevent damage to the guidewire, catheter, introducer sheath, or vessel.

HOW SUPPLIED

- Do not use if package is opened or damaged.
- Do not use if labeling is incomplete or illegible

The Peripheral Scoring Balloon Dilatation Catheter is supplied sterile and non-pyrogenic in an unopen, undamaged package. It is intended for single use only.

STORAGE

Store in a cool, dry, dark place. Do not expose to organic solvents, ionizing radiation or ultraviolet light. Rotate inventory so that products are used prior to the "Use By" date specified on the package label.

STERILIZATION

EO Sterilization

SHELF LIFE

36months

DEVICE LIFETIME

The lifetime of the device comprises its shelf life, and the time the device is in use:















Shelf life: 36months







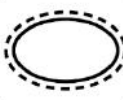

Time during which the device is in use: up to 1 hour.

DISPOSAL INSTRUCTIONS

Dispose of the product and packaging in accordance with the policy of the hospital, administration, and/or local government.

SYMBOLS AND EXPLANATION

Symbol	Title	Symbol	Title
	Model number		CE Marking
	Manufacturer		Keep away from sunlight
	Authorized representative in the European Community/European Union		Medical device
	Date of manufacture		Keep dry
	Use-by date		Temperature limit
	Batch code		Fragile, handle with care
	Do not re-use		Consult instructions for use or consult electronic instructions for use

Symbol	Title	Symbol	Title
	Sterilized using ethylene oxide		Caution
	Do not resterilize		Non-pyrogenic
	Do not use if package is damaged and consult instructions for use		Unique device identifier
	Single sterile barrier system with protective packaging outside		Contents

MANUFACTURER



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For any PMS information such as complaints, adverse event, etc., please contact the information above.

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